JUN 1 5 2001

K011534

6) **510(k) SUMMARY** **Date prepared: May 14, 2001**

Company Name and Address

Aspect Medical Systems, Inc.
141 Needham Street
Newton, MA 02464

Contact Person: ChristineVozella
Director, RA/QA

Device Name

Proprietary Names: A-2000™ EEG Monitor with BIS, and
BIS Engine (PCB component in an EEG monitor)
Common Name: EEG Monitor

Classification

Electroencephalograph (EEG) monitors have been classified by the Neurological Devices Panel as Class II devices (21 CFR 882.1400)

Predicate Devices

Predicate Devices:

Aspect Medical Systems EEG Monitor, Model A-2000 with BIS ™.
This 510(k), #K974496, received FDA clearance 2/6/98.

Aspect Medical Systems BIS Engine. This 510(k), #K002837, received FDA clearance 9/19/00.

Aspect Medical Systems EEG Sensor and DSC. This 510(k), K994330, received FDA 510(k) clearance 1/18/00.

DESCRIPTION

A-2000 EEG Monitor with BIS

A-2000 EEG Monitor with BIS (hereafter referred to as the A-2000 BIS Monitor) is an easy to use, microprocessor- based, 2 channel maximum EEG monitoring system. Its configuration consists of a Monitor, Digital Signal Converter (DSC), cables, electrodes, and an optional printer.

The Aspect A-2000 Monitor dimensions are 7 inches wide x 6.6 inches high x 4 inches deep. The active display area is 3.4 inches high x 4.5 inches wide, and displays the following:

- Raw EEG waveforms
- Density Modulated Spectral Array (DSA) (includes spectral edge frequency)
- Trend plots of processed EEG parameters in real time
- Current BIS number
- Signal quality and EMG indicators
- Suppression Ratio

DSC

The DSC is an electrically isolated, low noise, high gain amplifier that filters and digitizes up to two (2) channels of EEG waveform data. It is composed of two printed circuit boards, the preamplifier board and the communications board.

The DSC automatically configures via patient interface cables (PICs), has continuous impedance checking, and can detect when a lead has become disconnected. It is connected to the front of the monitor via a detachable cable. Its dimensions are: 2.50 x 3.75 x 1.00", and its weight is 4.5 ounces.

BIS Engine

The BIS Engine processor and software are substantially the same as the processor in the A-2000 BIS. The BIS Engine, which provides a means for incorporating Aspect's BIS technology into OEM (other equipment manufacturer's, i.e. our business partner's) finished devices, will also incorporate this change. The BIS Engine is a printed circuit board (PCB) that can either reside inside the OEM finished device or is redesigned for smaller size and packaged in a housing that will connect to the OEM finished device. It also allows for 2 channel maximum EEG monitoring.

INDICATIONS FOR USE

The Aspect A-2000 EEG Monitor with BIS System and BIS Engine are intended to monitor the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room and for clinical research.

The BIS, a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

Similarities/Differences

Similarities

The following are identical to their respective predicate devices:

Intended use	Signal flow
System technology	EEG Processing
Self-tests	BIS Algorithm
Display features	Display parameters
Alarm and alarm conditions	# of channels
Dimensions	

Minor Differences

The software and hardware technology is very similar. The only minor differences are explained below, and are due to the improvement in signal processing in the presence of electrocautery.

- The DSC-version 3 is being modified by making hardware changes that affect filtering and reduce demodulation.
- An electrocautery detector is being added to the DSC hardware. This indicates when an electrocautery device is in use.
- The A-2000 BIS Monitor and BIS Engine software are being modified slightly to accommodate the addition of the electrocautery detector. The BIS calculation/algorithm remains unchanged.

Summary of Test Results:

Results of Hazard Analysis: The hazard analysis results indicate that although there are changes to the hazard analysis, there are no changes that warrant additional tracking or risk management due to a higher risk level.

Results of the software validation: Pass

Results of the hardware validation: Pass

Results of the bench testing to show the improvement: Pass

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Christine M. Vozella
Director, Regulatory Affairs, Quality Assurance
Aspect Medical Systems, Inc.
141 Needham Street
Newton, Massachusetts 02464

Re: K011534
Trade/Device Name: EEG BIS Monitor Model A-2000 and BIS Engine
Regulation Number: 882.1400
Regulatory Class: II
Product Code: GWQ
Dated: May 17, 2001
Received: May 18, 2001

Dear Ms. Vozella:

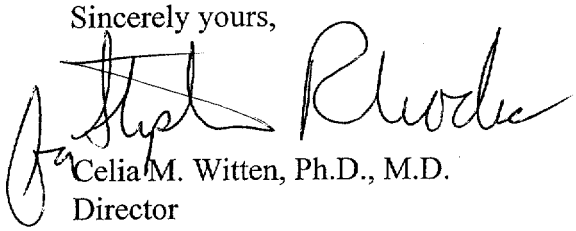
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011534

Device Name: EEG BIS Monitor (model A-2000) and BIS Engine (includes DSC-XP) (includes BIS Module)

Indications For Use:

Indicated for monitoring the state of the brain by data acquisition of EEG in the intensive care unit, operating room and for clinical research.

The BIS, a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011534

(Optional Format 3-10-98)